IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANDOZ INC. and RAREGEN, LLC *Plaintiffs*, v. UNITED THERAPEUTICS CORPORATION and SMITHS MEDICAL ASD, INC. *Defendants*.	Case No. 19-cv-10170-BRM-LHG

DECLARATION OF ROBERT SPINA

I, Robert Spina, declare as follows under 28 U.S.C. § 1746:

1. I am the Vice President for Key Accounts and Sales at Sandoz, Inc. ("Sandoz"). I work at Sandoz' offices located at 100 College Rd. West, Princeton, New Jersey 08540. I submit this declaration based on my personal knowledge and my review of records.

2. Sandoz is a division of the Novartis Group. As a leading provider of generic pharmaceuticals, Sandoz manufactures and sells generic and biosimilar medicines across the world. The company is committed to providing patients with access to affordable medications.

3. Sandoz has committed substantial personnel time and money to pursuing a generic injected treprostinil product. Treprostinil treats a life-threatening

disease known as pulmonary arterial hypertension ("PAH"), which causes high blood pressure in the arteries running from the heart to the lungs.

4. United Therapeutics Corporation ("UTC") markets and sells a branded treprostinil product, known as Remodulin®. As an injected form of treprostinil, Remodulin® can be administered in two forms: (1) directly into a patient's veins (by intravenous injection), or (2) under a patient's skin (by subcutaneous injection).

5. In 2011, Sandoz submitted the first Abbreviated New Drug Application ("ANDA") to the FDA requesting permission to market generic treprostinil for subcutaneous and intravenous administration. The Sandoz ANDA included a certification that the UTC patents connected to Remodulin® were invalid or otherwise would not be infringed by Sandoz' generic treprostinil. In response, UTC sued Sandoz for patent infringement under the Hatch-Waxman Act. Sandoz and UTC agreed to settle that suit in September 2015. By the terms of the settlement agreement, Sandoz received the contractual right to start marketing its generic treprostinil in the United States as early as June 2018.

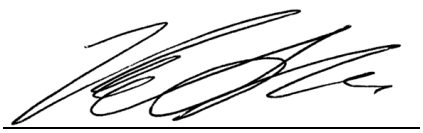
6. In November 2017, the FDA approved the Sandoz ANDA for generic treprostinil. In doing so, the FDA found that Sandoz' generic treprostinil and branded Remodulin® are therapeutically equivalent. This was the first time that the FDA had ever approved a generic formulation of injectable treprostinil.

7. Under the Hatch-Waxman Act, as the first-to-file generic, Sandoz is entitled to 180 days of exclusivity following its first sale of generic treprostinil. During that six-month period, there can be no other generic version of Remodulin® sold in the United States.

8. In August 2018, Sandoz and RareGen, LLC ("RareGen") partnered to market Sandoz' generic injected treprostinil in the United States. Under the terms of the Sandoz-RareGen agreement, Sandoz is responsible for providing a sufficient supply of generic treprostinil, and RareGen is responsible for promoting use of the product.

9. On March 25, 2019, Sandoz and RareGen launched sales of generic treprostinil in the United States. To date, however, generic injected treprostinil is available only to patients receiving intravenous treatment. Because of restrictions on cartridges used with the CADD-MS® 3 infusion pump, patients receiving subcutaneous treatment do not have access to Sandoz' generic alternative.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 3rd day of October, 2019. By: 

Robert Spina